FORUM

Workshop Proceedings: Managing Conflict of Interest in Science. A Little Consensus and A Lot of Controversy

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There is no doubt that participants in the Conflict of Interest (COI) Workshop at the Society of Toxicology (SOT) 2005 Annual Meeting (New Orleans, 6–10 March 2005) engaged in a vigorous and useful exchange of diverse ideas and viewpoints. While there was consensus on the value and interest of this Workshop, there was less consensus and more controversy over many of the issues discussed during the Workshop, which included the distinction between bias and conflict, the success or failure of policies of disclosure, whether waivers should or should not be granted to conflicted individuals in order to seat a “balanced” committee with appropriate expertise, whether conflicted individuals retain the ability to recognize their own conflict, and more. The discussion left no doubt, however, that conflict of interest will remain an important and controversial issue in the scientific community for some time to come.

Defining Conflict of Interest

Scientists participate in a number of distinct activities that tend to raise COI issues. These activities include publication of research findings, peer review (research articles, grant proposals, promotion committees, etc.), scientific advisory committees, institutional review boards and regulatory review committees. Several possible definitions of COI have been proposed, all of which appear to be equally valid. Two of these definitions are: an individual has a COI when there is a conflict between his/her personal or institutional interest and his/her official duties in a position of responsibility or trust; or, an individual is in conflict if he/she owes a duty of loyalty or responsibility to two distinct entities or individuals, both of which are likely to be affected by the scientific activity in which the individual is engaged. The term “interest” can refer to a financial (i.e., employer, employee, consultant, stockholder, investor, etc.) or a non-financial interest/relationship (i.e., family member, mentor, mentee, professional colleague, co-author, etc.). Most existing COI policies address financial but not non-financial conflicts of interest; however, non-financial conflicts of interest are equally common and important, and they warrant, and will likely receive, more attention and a higher degree of scrutiny in the future.

The Inevitability of Bias: The Danger of Unmanaged Conflict of Interest

It is important to recognize the distinction between bias and conflict. Because scientists both generate and test scientific hypotheses, it is generally accepted that bias, but not conflict, is virtually inherent in the scientific enterprise. Although some may argue with this statement, it has in fact been tested and is supported by a significant body of behavioral research (Kirsch, 1999; Rosenthal, 1966; Rothman, 1991). For example, this research shows that the process of generating and testing a hypothesis (which is integral to the scientific process) engenders an expectation/bias in the mind of the scientist who develops the hypothesis. The following quote from Schneiderman (1991) aptly illustrates the point in a light-hearted manner: “I want the audience to know that I am not unbiased. I work for the National Cancer Institute […] and I am against cancer.” (p. 1625). Thus, it is reasonable to state that unintentional bias is pervasive and unavoidable in science and among scientists. It should be distinguished from intentional or undue bias, which is not acceptable and should be avoided. Conflict of interest can and should be avoided whenever possible, because it has the potential to weaken the integrity of the scientific process itself (i.e., the ability to objectively evaluate evidence/data that may...
support or refute a scientific hypothesis). Furthermore, tolerance and/or mishandling of COI could jeopardize the public trust in science and scientists, as well as the moral fabric of our society. Thus, scientists in general, including the participants at the SOT Workshop, feel that failure to disclose conflict of interest is not acceptable and mechanisms should exist to ensure and/or enforce transparency with regard to COI among scientists.

Scientific Collaboration and COI Policy

Conflicts of interest, both financial and non-financial, are potentially present in any academic, industry, government, or non-government institution. Several participants at the SOT Workshop argued that because scientists collaborate and interact extensively (in fact, such collaboration is strongly encouraged and in some situations required within and across scientific disciplines), compliance with COI policies would seriously restrict the activities of the most active (and perhaps most highly regarded) scientists. In the extreme case, if a scientist in a specific field interacted professionally with every other scientist in this field, he/she could be excluded from reviewing any manuscripts or grant proposals and from serving on any peer review or advisory committees, activities in which his/her expertise might have been crucial. Nevertheless, this is not a justification for tolerating conflict and not vigorously enforcing COI policy in scientific disciplines if it may simply require additional effort to find an equally qualified individual who is not conflicted relative to a specific scientific activity.

COI on Scientific Advisory Committees: The Question of Waivers

Scientific advisory committees play an important role in evaluating current and in developing future science policy in the U.S. The individuals who serve on scientific advisory committees are usually selected (1) because they have a high level of expertise relevant to the committee charge, (2) in order to achieve functional balance on the committee, or (3) in order to provide equal representation of diverse viewpoints or perspectives (The National Academies, 2003). Committee members are hired as “special government employees” and as such, they must conform with federal COI policy that prohibits participation by individuals who have a conflict of interest. Nevertheless, it is in this context that the policy of COI disclosure was developed. Thus, to allow an individual in conflict to serve on an advisory committee, a waiver of COI policy is granted, under condition that his/her conflict is fully disclosed. The practice of granting waivers is widespread, but remains controversial. At the SOT Workshop, panelists were divided on this issue. Those who were strongly and unconditionally opposed to this practice agreed there may be some cases where agencies establishing advisory panels might want to waive conflicts of interest to obtain the required expertise, but these exceptions are extremely rare. Others felt strongly that the policy of granting waivers was appropriate and necessary, in order to achieve desired representation and provide needed expertise on a committee.

The Role and Integrity of Industry-Sponsored Research

The role of industry toxicologists in generating data on chemical and pharmaceutical products has been viewed by some as being controversial. One industry representative at the SOT Workshop indicated that industry considers it an “ethical obligation” to carry out high-quality investigations on compounds that have been or are in the process of being commercialized. The point was made that numerous safeguards exist that help to ensure the quality and integrity of such industry-sponsored research, including the following: (1) test sponsors are expected (and encouraged) to publish favorable and unfavorable test results in peer-reviewed journals; (2) most journals require disclosure of industry funding; (3) peer review procedures; (4) test protocols are required and governed by EPA testing guidelines, Good Laboratory Practice regulations, and the Information Quality Act, which requires accuracy, reliability and full availability of data; (5) EPA has strict guidelines for reporting adverse effects; (6) suppression of unfavorable research findings could be resulting in the prospect of punishable civil liability; and (7) the scientific process in and of itself leads to independent testing and validation of research findings.

However, the previous assertions about industry-sponsored research were questioned at this SOT Workshop. Some studies on industry-sponsored research show that university faculty members with industry support are almost twice as likely to refuse to share research results or biomaterials with colleagues as faculty members without industry support (11% versus 6%, respectively), and other studies show that financial support from industry sources leads to positive outcomes for industry products. The transparency of industry research programs has also been questioned, because only a small fraction of industry-sponsored research is published in peer-reviewed literature or otherwise made accessible to the scientific community and the public. In fact, industry representatives at the SOT Workshop acknowledged that a significant fraction of industry research is submitted to EPA as “Confidential Business Information” during regulatory review, which prevents public disclosure of these research results. This is especially true in the crop protection industry during petitions by manufacturers for registration of new active ingredients as required under FIFRA. Furthermore, toxicology journals are not typically interested in the results of regulatory testing as performed according to governmental guidelines.

A Problem in Managing Conflict of Interest: Moral Blindness

Many scientific institutions have recently developed or are developing strategies and policies for handling COI issues.
By and large, these policies rely on disclosure as a mechanism to manage COI. Although such practice is now widespread and widely accepted, it has been argued that individuals in conflict more often than not have difficulty recognizing their own conflicts. Thus, even in individuals of high moral character, a perceptual blind spot may exist that prevents critical self-evaluation when conflict exists. If true, this raises a red flag for many policies of disclosure, since they are based on the assumption that a person in conflict will recognize and disclose the conflict, recuse himself or herself, or take other appropriate action to manage the conflict. If this is a false assumption, the public trust is likely to be violated many times over. Unfortunately, there is no easy solution to this problem. If one assumes instead that individuals are not capable of recognizing and passing judgment on their own conflicts, this assumption could support inappropriate and unethical practices with respect to committee appointments. In particular, the potential for abuse is still present, because a candidate for a scientific committee could be disqualified based on a “perceived” conflict of interest, while being denied the opportunity to question his/her disqualification because of susceptibility to “perceptual blindness.”

Looking to the Future: A Reform Agenda

Not surprisingly, the success or failure of policies of COI disclosure were one of the main topics of discussion at the SOT Workshop. Some scientists are deeply dissatisfied with such policies and believe they are failing to serve the public interest due to relatively low compliance. For example, a 1997 survey of 181 highly ranked scientific journals revealed that only 0.5% of >60,000 articles had COI disclosures (Krimsky and Rothenberg, 2001). Another recent study by the Center for Science in the Public Interest indicated that authors of 8% of all articles published in four leading journals failed to disclose existing COI issues (Center for Science in the Public Interest, 2004). Four papers were analyzed more closely (Goozner, 2004b). The authors of these four papers (Ayotte, 2004; Blumberg, 2004; Gulson, 2004; Owens, 2004) and the editor (Goehl, 2004) responded. In addition, COI issues on federal advisory committees are often ignored and/or excused through waivers and COI issues related to regulatory agency submissions (excepting those within the Food and Drug Administration [FDA]) are largely unregulated. In response to the apparent failure of COI policies based on disclosure, the Center for Science in the Public Interest has proposed to increase FDA’s authority not only in the design, but also in the execution of clinical trials, and also to reform FDA advisory committees (Center for Science in the Public Interest, 2005). The following two additional proposals are being considered: (1) establishment of a clinical trials registry that will control publication of clinical trial-related data; and (2) creation of an independent federal Office of Drug Safety. In fact, the rationale for some of these reforms has been challenged and some scientists believe that existing disclosure policies have been successful and are generally sufficient to protect both the public health and the integrity of scientific research.

COI: Looking Ahead

This goal of this Workshop was to raise awareness of the complexity of the issue of COI in the scientific community. It is hoped that the Workshop both increased understanding of these issues and raised questions about current and future policies regarding COI in science. It is beyond the scope of this report to make specific recommendations regarding future guidelines or activities within or beyond SOT, because consensus was not reached on these topics at the Workshop or in subsequent discussions by Workshop panelists. Nevertheless, the outcome of the Workshop may include, among other things, renewed interest in revising the SOT Code of Ethics.

At the close of the Workshop, several audience participants commended the SOT ELSI Specialty Section for organizing this Workshop, which was a useful forum for exchange of information and ideas. Needless to say, at the end of the day, the importance of conflict of interest in science and the consequence of neglecting this subject were made very clear, even if there are currently few answers to many questions about conflict of interest in science.

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REFERENCES


National Academies (2003). Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports. (www.nationalacademies.org/coi/BI-COI_FORM-0.pdf)


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**SUGGESTED ADDITIONAL READING**


